

HOGAN & HARTSON
L.L.P.

MARTIN J. HAHN
PARTNER
(202) 637-5926
MJHAHN@HHLAW.COM

COLUMBIA SQUARE
555 THIRTEENTH STREET, NW
WASHINGTON, DC 20004-1109
TEL (202) 637-5600
FAX (202) 637-5910

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BY ELECTRONIC MAIL

Mr. Arthur Neal
Director of Program Administration
National Organic Program
USDA-AMS-TMP-NOP
1400 Independence Ave., SW
Room 4008-So., Ag Stop 0268
Washington, DC 20250

**Re: Comments on USDA Docket No. TMD-04-01: National
Organic Program (NOP): Proposed Amendments to the
National List of Allowed and Prohibited Substances
(Crops and Processing)**

Dear Mr. Neal:

On behalf of our client, Martek Biosciences Corporation (Martek), we submit this comment on the proposed rule entitled, "National Organic Program (NOP): Proposed Amendments to the National List of Allowed and Prohibited Substances (Crops and Processing)," Docket No. TM-04-01 (RIN 0581-AC35). The proposed rule would amend the list of nonagricultural (nonorganic) substances allowed in food by including the generic product category of "microorganisms." We ask that the U.S. Department of Agriculture (USDA) clarify that the category of "microorganisms" also includes food grade byproducts derived from microorganisms that exhibit similar characteristics or functions as the microorganism.

The categorical inclusion of food grade byproducts of food grade microorganisms would correspond to the findings made by USDA to date that such byproducts are appropriate in organic handling. Moreover, the categorical inclusion of food grade byproducts would conserve the administrative resources of the agency over the long term by eliminating the need to review these byproducts on a substance-by-substance basis.

BRUSSELS BUDAPEST* LONDON MOSCOW PARIS* PRAGUE* WARSAW

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*Affiliated Office

I. BACKGROUND

In the proposed rule, USDA's Agricultural Marketing Service (AMS) seeks to amend the National List of Allowed and Prohibited Substances (National List), which identifies synthetic substances that may be used and the nonsynthetic substances that cannot be used in organic production and handling operations. Part of the National List is a delineation of the nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic" ingredients or food groups, which is codified in 7 C.F.R. § 205.605. 1/ The category, "Microorganisms—any food grade bacteria, fungi, and other microorganisms," is included among the substances proposed to be added to part (a) of this list (*i.e.*, Nonsynthetics allowed). 2/

The National Organic Standards Board (NOSB) proposed the broad category of food-grade microorganisms following the submission of a petition for the use of seed mold as a processing aid in organic handling. During its evaluation of seed mold, the NOSB:

[R]ecognized that they had previously evaluated and determined other types of food-grade microorganisms (*e.g.*, dairy cultures and yeast) and certain by-products derived from them (*e.g.*, enzymes) to be consistent with [Organic Foods Production Act of 1990] OFPA criteria and the NOP regulations. ... The NOSB acknowledged that there are many species of food-grade microorganisms that are used in food processing that could be petitioned for use in organic handling. As a result, a decision was made by the NOSB to evaluate the categorical use of food-grade microorganisms in organic handling and recommend their inclusion in section 205.605(a) of the National List. This decision would obviate the need for future review

1/ See 70 *Fed. Reg.* 54660 (Sept. 16, 2005).

2/ See *id.* at 54663.

and evaluation of other individual food grade microorganisms that exhibit similar characteristics and functions as those already approved for use on the National List 3/

The NOSB recognized that it already has included certain byproducts of food grade microorganisms on § 205.605(a) of the National List and the NOSB used such inclusion, in part, as its justification for adding microorganisms to the list. The NOSB did not specifically comment, however, on whether it intends to include byproducts that exhibit similar characteristics and functions as those of the microorganisms.

II. REQUEST TO CLARIFY THE SCOPE

We respectfully submit that the proposed regulation would be more complete if the category of substances, “Microorganisms—any food grade bacteria, fungi, and other microorganisms,” were defined as including any food grade byproducts of these microorganisms that exhibit similar characteristics or are used for the same function as the microorganism. The inclusion of food grade microorganism-derived byproducts would be consistent with previous findings made by the NOSB for one category of food grade byproducts: “Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.” These enzymes were included in § 205.605(a) of the initial version of the National List, which was issued in December 2000. 4/

Furthermore, the categorical inclusion of food grade byproducts derived from food grade microorganisms would help conserve the limited resources of the NOSB and the USDA. Similar to the discussion noted above for the categorical inclusion of food grade microorganisms, expanding the proposed rule to encompass food grade byproducts derived from these organisms would obviate the need for future review and evaluation of individual byproducts that exhibit similar characteristics and functions as those already approved for use on the National List

3/ *Id.*

4/ *See 65 Fed. Reg. 80547 (Dec. 21, 2000).*

(i.e., enzymes). The industry resources necessary to prepare petitions to amend the National List would be conserved as well.

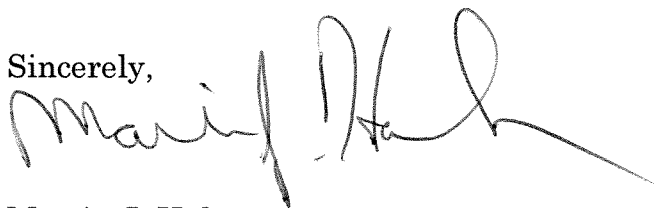
Martek manufactures a docosahexaenoic acid (DHA)-rich oil that is extracted from non-toxic strains of a single cell algae. Martek has two algal sources for its DHA oil, *Schizochytrium sp.* and *Cryptothecodinium cohnii*. DHA is an omega-3 fatty acid that is being added to infant formulas and various conventional foods to help increase dietary intake of this important nutrient. Low levels of Martek's DHA-rich oil are added to foods with typical use levels ranging in the 30 to 150 mg of DHA per serving.

Under the proposed rule, the dried algal biomass could be added to a food labeled as "organic" or "made with organic ingredients" because it is a food-grade microorganism. The dried biomass would be added for the specific purpose of increasing the DHA content of the finished food. In an instance such as this when the dried biomass could be added directly to the finished food, it would be reasonable to establish a regulatory framework that also would allow the DHA-rich oil extracted from the biomass to be added to foods labeled as "organic" or "made with organic ingredients" because the DHA-rich oil would be added for the same functional effect as the dried biomass. The NOSB would save valuable time and resources by clarifying that the listing of "microorganisms" also covers the food-grade products derived from such microorganisms.

* * * * *

For the reasons specified above, we respectfully submit that the category of food grade microorganisms currently proposed to be added to the National List under 7 CFR § 205.605(a) be clarified so as to include food grade byproducts derived from microorganisms when such byproducts exhibit similar characteristics or functions as the microorganisms.

Sincerely,

A handwritten signature in black ink, appearing to read "Martin J. Hahn", with a long horizontal flourish extending to the right.

Martin J. Hahn